U.S. 09/073,596
Reply to Office action of 10 February 2005

REMARKS/ARGUMENTS

Claims 82, 84-96 and 98-120 are pending. Claim 121 has been added. Claims 82, 85-88, 90, 93, 96, 98, 100 and 102 have been withdrawn as a result of an earlier restriction requirement. Applicants retain the right to present these withdrawn claims in a divisional application. Claims 84, 89, 91, 92, 94, 95, 99, 101 and 103-120 stand rejected.

Claims 94, 99, 101, 109, 110, 114, 115 and 120 have been amended. Claim 94 has been amended to correct an obvious typographical error. Support for the amendments to claim 99, 101, 115 and 120 can be found in the specification at in the specification at page 5, lines 23-30, page 6, lines 4-32 and at page 36, lines 13-15. Support for the amendment to claim 109 can be found in the specification at page 29, lines 20-35. Support for the amendment adding the term "molecules" to claims 114 and 115 can be found in the specification at page 5, lines 33-35. Support for new claim 121 can be found original claim 28 of the instant application. No new matter has been added.

The previous rejections of claims 84, 89, 91-92, 97, 99, 101 and 103 under 35 U.S.C. § 103(a) have been withdrawn.

Applicants thank the Examiner for the courtesy of a telephonic interview conducted on 6 June 2005. The rejections of claims 84, 89, 91-92, 94-95, 99, 101 and 103-120 under 35 U.S.C. § 112, first paragraph, for allegedly containing new matter was discussed. A final agreement was not reached.

I. The claims meet the requirements of 35 U.S.C. § 112, first paragraph.

Claim 109 was rejected under 35 U.S.C. § 112, first paragraph for an alleged lack of written description, for reasons of record. Specifically, the Office action states that this is a new matter rejection, and alleges that the specification and the claims as originally filed do not support the recitation of, "wherein the cell aggregates are subcultured *about* one to five times." (Office Action dated 10 February 2005, part 4.) The record (Office action dated 13 August 2004) indicates that the Office objects to the use of the term "about" in claim 109, which encompasses methods relating to bone marrow derived cell aggregates as well as to blood derived cell aggregates. The Action acknowledges support in the specification for subculturing blood derived population of cell aggregates about one to five times, but alleges that subculturing

the bone marrow derived cell aggregates about one to five times is not supported by the specification.

Applicants have amended claim 109 to specify that the cell aggregates are "blood derived". Support for subculturing blood derived cell aggregates about one to five times can be found in the specification at page 29, lines 20-35. Accordingly, Applicants respectfully submit that amended claim 109 does not present new matter, and that the rejection of claim 109 under 35 U.S.C. § 112, first paragraph may be properly withdrawn.

Applicants have added new claim 121, which specifies, "The composition of claim 101, wherein the cell aggregates are serially subcultured one to five times." Support for new claim 121 can be found in original claim 28 of the instant application, which recites: "The method of claim 21, wherein the cell aggregates of step (e) are serially subcultured one to five times." Applicants note that original independent claim 21 is directed to a method of producing a population of mature dendritic cells from proliferating cell cultures, comprising: providing a tissue source comprising dendritic cell precursors . . .", and was *not* limited to a "blood derived population" of dendritic cell precursors. The preamble of original claim 21 recites a method of producing a population of mature dendritic cells, while pending claim 101 recites a composition comprising antigen-activated dendritic cells. However, it is clear that the antigen-activated dendritic cells recited in claim 101 can be mature dendritic cells, as evidenced by the original abstract at page 101 of the specification, which recites: "The cultures of mature dendritic cells provide an effective means of producing novel T cell dependent antigens comprised of dendritic cell modified antigens or dendritic cells pulsed with antigen, including particulates, which antigen is processed and expressed on the antigen-activated dendritic cell."

Support for "wherein the cell aggregates are subcultured one to five times" in new claim 121 can also be found in original claim 4 of the first priority application (U.S. Ser. No. 07/861,612), which recites: "The method according to claim 3, wherein the cell aggregates of step (e) are serially subcultured one to five times. Claim 3 of the 07/861,612 application specifies that the tissue source is blood *or* bone marrow, and is dependent upon claim 1, which is directed to a method of producing a population of dendritic cell precursors from proliferating cell cultures. Accordingly, new claim 121 does not contain new matter.

Claims 84, 89, 91-92, 94-95, 99, 101 and 103-120 stand rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description (Office Action dated 10 February 2005, part 5). Specifically, the Action alleges that the recitation of "a composition comprising an enriched and expanded population of antigen-activated dendritic cells" in claims 101 and 120 is new matter, as set forth previously. A previous Office action dated 3 February 2004, at part 10, alleges that the specification only supports "an enriched and expanded population of *dendritic cell precursors*", but *not* "an enriched and expanded population of antigen-activated *dendritic cells*" as specified in independent claims 101 and 120. In addition, the Action alleges that the recitation of "a modified antigen" in claim 101 and "antigen modification" in claim 120 constitutes new matter.

Applicants respectfully submit that "a modified antigen" and "antigen modification" is not new matter, as support for these terms can be found in the specification at page 10, lines 7-10, which recites, "the antigen is modified by the dendritic cells to produce modified antigens which are immunogenic fragments of the unmodified or native antigen. . ." However, in order to expedite prosecution, claim 101 has been amended to specify: "An in vitro composition comprising *antigen-activated dendritic cells* presenting *fragmented* antigen derived from an in vitro culture of an *enriched and expanded population of proliferating dendritic cell precursors* by a method comprising: . . ." . Claim 120 has been similarly amended, but specifies "antigen fragmentation". In addition, claims 99 and 115 have been amended to replace the term "modified antigen" with "fragmented antigen". The Examiner has previously acknowledged that the specification provides support for "an enriched and expanded population of *dendritic cell precursors*" (Office action dated 3 February 2004, at part 10). Support for "fragmented antigen" and "antigen fragmentation" can be found in the specification at page 5, lines 23-30, page 6, lines 4-32 and at page 36, lines 13-15. Thus, claims 101 and 120 no longer recite "an enriched and expanded population of antigen-activated *dendritic cells*", "a modified antigen" nor "antigen modification. Accordingly, the rejection of claim independent claim 101, dependent claims 84, 89, 91-92, 94-95, 99, 103-119 and independent claim 120 under 35 U.S.C. § 112, first paragraph, for containing new matter may be properly withdrawn.

Claim 110 stands rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description (Office Action dated 10 February 2005, part 8). Specifically, the Action alleges that the recitation of "wherein the cell aggregates are subcultured about every 3 to 30

days" in claim 110 is new matter, as set forth previously. The Office Action dated 3 February 2004 (at part 12), alleges that the specification discloses this limitation only for a "blood derived population of dendritic cells".

Claim 110 has been amended to delete the term "about". Applicants respectfully submit that support for the limitation "wherein the cell aggregates are subcultured every 3 to 30 days" as applied to both bone marrow derived dendritic cells and blood derived dendritic cells can be found in claim 14 as originally filed. Original claim 14 recites, "wherein the tissue source is blood or bone marrow . . . , the *cell aggregates are serially subcultured* one to five times *every 3 to 30 days*. This same language is also found in original claim 10 of the priority application (U.S. Patent App. No. 07/861,612). Accordingly, the rejection of claim 110 under 35 U.S.C. § 112, first paragraph for containing new matter may be properly withdrawn.

Claim 115 stands rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description (Office Action dated 10 February 2005, part 8). Specifically, the Action alleges that the recitation of "wherein said modified antigen is presented by the dendritic cells on MHC class I or MHC class II" in claim 115 is new matter, as set forth previously. The Office Action dated 3 February 2004 (at part 12), alleges that the specification discloses this limitation only for a microbial, "other" and recombinant viral antigens.

Claim 115 has been amended to specify that the *fragmented* antigen is presented by the dendritic cells on MHC class I or MHC class II *molecules*. Applicants respectfully submit that amended claim 115 is fully supported by the specification, which discloses that fragmented antigens are presented is association with MHC molecules, of which there are two types, class I and class II (see page 5, lines 27-35). Furthermore, the specification states at page 12, lines 2-5, "This invention additionally provides a method comprising the use of mature and precursor dendritic cells to present MHC class I and II products with antigen peptides." None of these foregoing descriptions in the specification are limited to microbial, "other" or recombinant viral antigens. Accordingly, the rejection of claim 115 under 35 U.S.C. § 112, first paragraph, for containing new matter may be properly withdrawn.

Claims 118 and 119 stand rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description (Office Action dated 10 February 2005, part 8). Specifically, the Action alleges that the recitation of "wherein the dendritic cell precursors are cultured in the

presence of antigen" is new matter, as the specification allegedly discloses this limitation only for a "particulate matter" (see Office action dated 13 August 2004, part 12).

Applicant's respectfully traverses this rejection. Support for "wherein the dendritic cell precursors are cultured in the presence of antigen" can be found in original claim 65, which recites, "A method of preparing an antigen fragment from an antigen comprising contacting the antigen with cells selected from the group consisting of dendritic cells and dendritic cell precursors, incubating the cells with the antigen for sufficient time to allow the cells to process the antigen into the fragments and present the antigen fragment on the cell surface. In addition, the specification discloses at page 10, lines 13-23, "contacting the precursor cells with antigen for a period of time sufficient to allow the dendritic cell precursors to phagocytose the antigen . . ."; and at page 12, lines 26-29, "It is also an object of the invention to provide dendritic cell precursors capable of phagocytosing antigenic material to be processed and presented by the dendritic cell precursors". None of these foregoing descriptions in the specification are limited to "particulate matter". Accordingly, the rejection of claims 118 and 119 under 35 U.S.C. § 112, first paragraph, for containing new matter may be properly withdrawn.

II. Non-Statutory Double Patenting Rejection

Claims 84, 89, 91-92, 94-95, 99, 101 and 103-120 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 45 and 46 of the copending and later filed U.S. Patent Application No. 10/287,813.

The Examiner has acknowledged that Applicants have requested that this ground for rejection be held in abeyance until allowable subject matter is indicated.

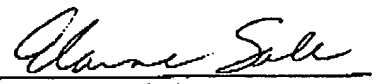
CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the claims are in condition for allowance. However, if the Examiner believes that any further discussion of this communication would be helpful, he is encouraged to contact the undersigned by telephone.

A Request for Continued Examination, a Petition for an Extension of Time of two months and the required fees are submitted herewith. No additional fees are believed to be due

in connection with this communication. However, please apply any charges or credits that may be due to our Deposit Account No. 50-3187.

Respectfully submitted,



Elaine Sale, Ph.D.
Attorney for Applicants
Registration No. 41,286

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Argos Therapeutics, Inc.
4233 Technology Drive
Durham, NC 27704
Tel: (919) 287-6332
Fax: (919) 287-6301